



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,557	01/06/2005	Moon-Hee Sung	4240-116	5278

23448 7590 12/18/2009
INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER

HELM, CARALYNNE E

ART UNIT	PAPER NUMBER
----------	--------------

1615

MAIL DATE	DELIVERY MODE
-----------	---------------

12/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,557	Applicant(s) SUNG ET AL.	
	Examiner CARALYNNE HELM	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-20 is/are pending in the application.
- 4a) Of the above claim(s) 4-14,19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1615

DETAILED ACTION

Election/Restrictions

To summarize the current election, applicant elected Group I. Claims 4-14 were withdrawn from further consideration. New claims 19 and 20 are also withdrawn since they are drawn to nonelected inventions.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 18 recite “high” moisture absorbing properties, moisture retaining properties and calcium solubility. The term "high" in claim 1 and 18 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Additionally, it is unclear what attribute is claimed in the “moisture absorbing property” recited. Claim 15 recites at least a 60% increase in water content over 24

Art Unit: 1615

hours but specifies no conditions or environment in which this absorption occurs and is measured (e.g. the source of the water is not recited). In addition, it is not clear if the 60% is relative to the initial weight of the poly(gamma glutamate) (PGA) (e.g. corresponds to a 60% increase in weight of a previously dry PGA sample after 24 hrs exposure to the specified conditions) or the total amount of water that is present in the system.

Claims 1 and 16 recites retention of water in a material that does not recite the presence of water. Again, applicants have omitted the conditions/environment under which this property occurs. In the absence of this information, the recitation provides little to allow one of ordinary skill to ascertain the claim's metes and bounds.

While applicants are free to be their own lexicographer, the "Ca solubility" property recited in claims 1 and 17-18 is not well defined. The measurement and comprehension of this property is wholly dependent on the assay applicants utilized. The value claimed for this "solubility" is meaningless outside the particular conditions and formulations applicants tested, but none of these testing conditions or formulations are recited in the claim. Thus the "at least 46%" has no basis or frame of reference. It appears that applicants intend to describe the ability of the PGA to absorb calcium ions; however, the current recitation has not done so in a comprehensible fashion.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1615

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Diiorio et al. (previously cited).

Diiorio et al. disclose a gamma-poly(glutamic acid) (also known as poly(gamma glutamate)) whose molecular weight is approximately 8,000,000 g/mol which corresponds to 8000 kDa (see page 11 line 32-page 12 line 5 and example V; instant claims 1-2). Instant claim 1 recites a product by process, where the claimed polymer is made by a particular bacterial strain. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. The process of making the polymer in instant claim 1 does not add any structure to the claimed compound and thus does not garner patentable weight. According to MPEP 2112.01, “A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.” This treatment results from In re Spada, which states that, “Products of identical chemical composition can not have mutually exclusive properties.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicants have provided no evidence

Art Unit: 1615

distinguishing the PGA derived from their preferred source from PGA disclosed in Diiorio et al. The molecular weight of the material of Diiorio et al. meets the limitations of applicants' claim and therefore their PGA would have the same properties as instantly claimed (see instant claims 1 and 15-17). Therefore claims 1-2 and 15-17 are unpatentable over Diiorio et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

Art Unit: 1615

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diiorio et al.

Diiorio et al. teach a PGA whose molecular weight is can rage from 2500 kDa to 100,000 kDa (see page 11 line 32-page 12 line 5 and example V). Additional particular molecular weights are taught that include 10,000 kDa (see page 12 line 3). In addition, Diiorio et al. also teach that the molecular weight can be obtained using different formulations of broth for the cells that generate the polymer (see example II). In addition, Diiorio et al. also contemplate routine experimentation to yield variations of the specific embodiments taught as being within the scope of their invention (see page 19). While Diiorio et al. do not explicitly teach a 13,000 kDa PGA, this molecular weight falls within the range taught and would have been achieved as matter of routine experimentation by one of ordinary skill in the art at the time of the invention. Instant claim 18 recites a product by process, where the claimed polymer is made by a particular bacterial strain. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art,

Art Unit: 1615

the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) see MPEP 2113. The process of making the polymer in instant claim 18 does not add any structure to the claimed compound and thus does not garner patentable weight. Further, according to MPEP 2112.01, “A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.” This treatment results from In re Spada, which states that, “Products of identical chemical composition can not have mutually exclusive properties.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicants have provided no evidence distinguishing the PGA derived from their preferred source from PGA disclosed in Diorio et al. Therefore a 10,000 kDa as well as a 13,000 kDa PGA from the invention of Diorio et al. would also have the same properties (see instant claims 1 and 15-18). Therefore claims 1 and 15-18 is obvious over Diorio et al.

Response to Arguments

Applicants’ arguments filed September 10, 2009, with respect to the provisional double patenting rejections have been fully considered and are persuasive. Applicant’s arguments regarding the rejection under 35 USC 102(b) are not persuasive.

Applicants argue that the process recited in the product claims under examination impart distinctive structural characteristics to the final product; However applicants have provided no evidence to support this assertion. Although applicants

Art Unit: 1615

point to the examples in the disclosure that compare the PGA of the instant invention other PGA polymers, none of these polymers have the same molecular weight as that instantly claimed. Applicants do not address the source of these polymers and there is no evidence of record to demonstrate that the method of making these polymers has any bearing on their functionality. While there are differences in function of the other PGA polymers tested, it cannot be concluded that this difference is due to the method of making the polymer. In fact applicants appear to be pointing to the molecular weight of the polymers, and not their source, as the key feature of concern in the invention that facilitates their desired functionality. Therefore since the polymer of Diiorio et al. is the same as that claimed with the same molecular weight, absent evidence to the contrary, it would have had the same properties.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The rejections and/or objections detailed above are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1615

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615